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BY ELECTRONIC FILING

The Honorable Richard G. Andrews
U.S. District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Room 6325, Unit 9
Wilmington, DE 19801-3556

Re: *Andrulis Pharmaceuticals Corporation v. Celgene Corporation*, C.A. No. 13-1644 (RGA)

Dear Judge Andrews:

Defendant Celgene Corporation seeks leave to file an early motion for partial summary judgment that the alleged third-party use of Revlimid®—the larger-selling of the two accused products in this case—does not infringe the only asserted claim in U.S. Patent No. 6,140,346 ("'346 patent"). When Celgene discussed this motion during the May 13, 2014 conference, the Court indicated it was amenable to Celgene submitting this request, and the Court included requests for leave to file early summary judgment motions in the subsequent Scheduling Order. (5/13/14 Tr. at 16:1–30:14, 28:10–30:9; D.I. 30 at ¶ 11.) In addition, Plaintiff Andrulis Pharmaceuticals Corporation indicated that it would be "amenable to the briefing." (5/13/14 Tr. at 29:19–20.) As discussed in more detail below, Celgene's early summary judgment motion is appropriate because Andrulis concedes that Revlimid® does not literally infringe and because prosecution history estoppel is a purely legal issue based on indisputable facts that bars Andrulis's allegation that Revlimid® infringes under the doctrine of equivalents. By deciding the non-infringement of Revlimid® now, the Court would substantially streamline discovery and may drive an early resolution because Celgene's total sales of Revlimid® are more than seven times the total sales of the other accused product (Thalomid®, which includes the claimed drug, thalidomide).

Summary judgment of no literal infringement is appropriate. The asserted claim requires use of "thalidomide," among other things. Lenalidomide, the active pharmaceutical ingredient of Revlimid®, is not literally thalidomide, which precludes literal infringement. Andrulis admits that lenalidomide is not literally thalidomide.

Prosecution history estoppel, a pure legal issue, precludes Andrulis's infringement allegations under the doctrine of equivalents. Prosecution history estoppel is a question of law that is based on an indisputable prosecution history record; it is thus well-suited to summary judgment. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) (en banc). During prosecution, the Patent Office rejected Andrulis's attempts to claim non-thalidomide molecules for lack of enablement under 35 U.S.C. § 112, ¶ 1. Andrulis did not challenge that rejection and ultimately canceled its broader claims to other molecules, never to pursue them again. Under the doctrine of prosecution history estoppel, Andrulis cannot now accuse as infringing purported equivalents of thalidomide.

Prosecution history estoppel presumptively bars any allegation that lenalidomide infringes as a purported equivalent to thalidomide. Andrulis's original claims recited a genus of molecules that included "tumor necrosis factor alpha (TNF-alpha) inhibitors." (Ex. 1) Thalidomide and lenalidomide are TNF-alpha ("TNF-α") inhibitors. In July 1996, the Patent Office rejected the genus claims as non-enabled, holding that "[s]ince no other inhibitors [besides thalidomide] are disclosed, those of ordinary skill could not practice the invention . . . except with thalidomide." (Ex. 2.) Thereafter, Andrulis limited its claims to thalidomide and, in a continuation application, ultimately abandoned all attempts to patent other molecules.

When a patentee narrows claims from a genus to a species after an enablement rejection, prosecution history estoppel restricts claim scope to the species. *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348 (Fed. Cir. 2004). In *Glaxo*, some original claims recited a genus (sustained release agents) while others recited a species (hydroxyproplylmethylcellulose ("HPMC")). Like here, the Patent Office rejected the genus claims because the specification enabled just one molecule, HPMC. *Id.* at 1352. The patentee acquiesced, amending all claims to require HPMC. *Id.* It later tried to recapture hydroxypropylcellulose ("HPC") via the doctrine of equivalents. *Id.* The Federal Circuit held that estoppel applied. By narrowing the claims to HPMC after the enablement rejection (in the same way that Andrulis narrowed its claims), the patentee surrendered all non-HPMC compounds, including HPC. *Id*. As in *Glaxo*, Andrulis never challenged, much less overcame, the enablement rejection of the genus claims. Instead, Andrulis pursued only claims limited to thalidomide, and in 2000 canceled its genus claims to obtain the '346 patent, never pursuing claims to the genus or any other molecule.

It is irrelevant that the enablement rejection occurred in a parent application. Where, as here, the patentee fails to recapture subject matter surrendered or disclaimed in a parent application, the prosecution history as a whole supports estoppel. *See Mark I Mktg. Corp. v. Donnelley & Sons Co*., 66 F.3d 285, 291–92 (Fed. Cir. 1995); *see also Hakim v. Cannon Avent Group plc*, 479 F.3d 1313, 1317 (Fed. Cir. 2007). Likewise, it does not matter that canceling the genus claims in 2000 also resolved a requirement that Andrulis restrict its application to a single invention. While restriction requirements might not *per se* trigger estoppel, where the prosecution history as a whole makes clear, as here, that the patentee surrendered the scope of the canceled claims, the doctrine applies. *See Merck & Co., Inc. v. Mylan Pharms., Inc*., 190 F.3d 1335, 1341–42 (Fed. Cir. 1999).

Andrulis cannot rebut the presumption. A patentee can rebut presumptive estoppel only if it can show one of three narrow factors: (1) the alleged equivalent was unforeseeable at

the time of the narrowing amendment; (2) the rationale for the amendment or surrender bore no more than a tangential relation to the equivalent in question; or (3) some other reason suggested that the patentee could not reasonably have been expected to describe the alleged equivalent. Andrulis cannot show any of these factors.

1) Lenalidomide was known and foreseeable. Andrulis foresaw other inhibitors, including lenalidomide. Andrulis tried to claim all TNF-α inhibitors (although, as the prosecution history shows, it overreached in doing so). After trying to claim them all, Andrulis cannot allege that other TNF-α inhibitors besides thalidomide were unforeseeable. In fact, lenalidomide itself was known in 2000, when Andrulis abandoned its claims to other molecules. Celgene's Muller patent, which was filed in July 1996 and issued in June 1997, disclosed the use of lenalidomide as a TNF-α inhibitor.

2) The amendment was not tangential to lenalidomide. Tangentiality asks if the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent. Here, Andrulis narrowed its claims for reasons directly related to whether the claims could properly extend beyond thalidomide because the Patent Office held that only thalidomide was enabled.

3) No "other reason" permits recapture. The only other way a patentee can avoid estoppel is to show some "other reason," such as linguistic shortcomings, why it could not describe the alleged equivalent when it amended its claims. Here, the original (and non-enabled) genus claims reached all TNF-α inhibitors, including lenalidomide. Thus, no linguistic or "other reason" negates estoppel.

Celgene's proposed motion will largely resolve the case and eliminate the need for discovery on Revlimid®. If granted, Celgene's motion would resolve all infringement allegations based on Revlimid® and thereby largely resolve this case by narrowing the scope of this case to Thalomid®. As such, summary judgment of noninfringement as to Revlimid® may facilitate the parties' voluntary resolution of the case. Even if the case is not fully resolved, granting Celgene's motion will greatly narrow the case. The claims have not yet been construed (and Andrulis's recently-served claim construction brief confirms that no claim construction is needed to resolve this motion). Fact discovery continues until June 2015, and expert discovery does not begin until August 2015. Given its significantly greater sales, Revlimid® will likely require more extensive discovery than Thalomid®.

Indeed, a stay of discovery as to Revlimid® while the motion is pending would further conserve judicial and party resources. Staying discovery as to Revlimid® would avoid wasteful litigation concerning equivalence allegations that are barred as a matter of law. Such a stay would cause no prejudice. Andrulis does not compete with Celgene, and there is no prospect of injunctive relief because the '346 patent expires a year before trial. Should the Court grant leave to file the proposed summary judgment motion, Celgene would file a separate motion to stay.

For the foregoing reasons, Celgene submits that it should be granted leave to file its proposed summary judgment motion of noninfringement as to Revlimid®.

Respectfully,

/s/ Mary B. Graham

Mary B. Graham (#2256)

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cc: Counsel of Record
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